



Europäisches Patentamt

(19)

European Patent Office

Office européen des brevets

(11) Publication number:

0 145 166

A2

(12)

EUROPEAN PATENT APPLICATION

(21) Application number: 84306982.4

(51) Int. Cl.4: A 61 F 5/00
A 61 L 27/00

(22) Date of filing: 12.10.84

(30) Priority: 14.10.83 US 541852

(71) Applicant: RAYCHEM CORPORATION
300 Constitution Drive
Menlo Park California 94025(US)

(43) Date of publication of application:
19.06.85 Bulletin 85/25

(72) Inventor: Jervis, James
496 Welsh Road
Atherton California 94025(US)

(60) Designated Contracting States:
AT BE CH DE FR GB IT LI NL SE

(74) Representative: Benson, John Everett et al,
Raychem Limited Intellectual Property Law Department
Swan House 37-39, High Holborn,
London WC1(GB)

(54) Shape memory alloys.

(57) Medical devices which are currently proposed to use elements made from shape memory alloys may be improved by the use of stress-induced martensite alloy elements instead. The use of stress-induced martensite decreases the temperature sensitivity of the devices, thereby making them easier to install and/or remove.

Best Available Copy

EP 0 145 166 A2

DESCRIPTION

SHAPE MEMORY ALLOYS

This invention relates to medical devices incorporating shape memory alloys, and to improvements therein.

Materials, both organic and metallic, capable of possessing shape memory are well known. An article 5 made of such materials can be deformed from an original, heat-stable configuration to a second, heat-unstable configuration. The article is said to have shape memory for the reason that, upon the application of heat alone, it can be caused to revert, or to attempt 10 to revert, from its heat-unstable configuration to its original, heat-stable configuration, i.e. it "remembers" its original shape.

Among metallic alloys, the ability to possess shape memory is a result of the fact that the alloy undergoes 15 a reversible transformation from an austenitic state to a martensitic state with a change in temperature. This transformation is sometimes referred to as a thermo-elastic martensitic transformation. An article made from such an alloy, for example a hollow sleeve, is 20 easily deformed from its original configuration to a new configuration when cooled below the temperature at which the alloy is transformed from the austenitic state to the martensitic state.

The temperature at which this transformation begins is 25 usually referred to as M_s and the temperature at which it finishes M_f . When an article thus deformed

is warmed to the temperature at which the alloy starts to revert back to austenite, referred to as A_s (A_f being the temperature at which the reversion is complete) the deformed object will begin to return to its original 5 configuration.

Many shape memory alloys (SMAs) are known to display stress-induced martensite (SIM). When an SMA sample exhibiting stress-induced martensite is stressed at a temperature above M_s (so that the austenitic state is 10 initially stable), but below M_d (the maximum temperature at which martensite formation can occur even under stress) it first deforms elastically and then, at a critical stress, begins to transform by the formation of stress-induced martensite. Depending on whether the 15 temperature is above or below A_s , the behavior when the deforming stress is released differs. If the temperature is below A_s , the stress-induced martensite is stable; but if the temperature is above A_s , the martensite is unstable and transforms back to austenite, 20 with the sample returning (or attempting to return) to its original shape. The effect is seen in almost all alloys which exhibit a thermoelastic martensitic transformation, along with the shape memory effect. However, the extent of the temperature range over which 25 SIM is seen and the stress and strain ranges for the effect vary greatly with the alloy.

In U.S. Patent Application No. 541844, the disclosure of which is incorporated herein by reference, a nickel/titanium/vanadium alloy having SIM over a wide temperature range is disclosed.

Shape memory alloys have found use in recent years in, for example, pipe couplings (such as are described in U.S. Pat. Nos. 4,035,007 and 4,198,081 to Harrison and Jervis), electrical connectors (such as are described 5 in U.S. Pat. No 3,740,839 to Otte & Fischer), switches (such as are described in U.S. Patent No. 4,205,293), actuators, etc.

Various proposals have also been made to employ shape memory alloys in the medical field. For example, U.S. 10 Pat. No. 3,620,212 to Fannon et al. proposes the use of an SMA intrauterine contraceptive device, U.S. Pat. No. 3,786,806 to Johnson et al. proposes the use of an SMA bone plate, U.S. Pat. No. 3,890,977 to Wilson proposes the use of an SMA element to bend a catheter or cannula, 15 etc.

These medical SMA devices rely on the property of shape memory to achieve their desired effects. That is to say, they rely on the fact that when an SMA element is cooled to its martensitic state and is subsequently 20 deformed, it will retain its new shape; but when it is warmed to its austenitic state, the original shape will be recovered.

However, the use of the shape memory effect in medical applications is attended with two principal disadvantages. 25 First, it is difficult to control the transformation temperatures of shape memory alloys with accuracy as they are usually extremely composition-sensitive, although various techniques have been proposed (including the blending by power metallurgy of already-made alloys 30 of differing transformation temperatures: see U.S. Pat. No. 4,310,354 to Fountain et al.). Secondly, in many shape memory alloys there is a large hysteresis

as the alloy is transformed between austenitic and martensitic states, so that reversing of the state of an SMA element may require a temperature excursion of several tens of degrees Celsius. The combination of 5 these factors with the limitation that (a) it is inconvenient to have to engage in any temperature manipulation, and (b) human tissue cannot be heated or cooled beyond certain relatively narrow limits (approximately 0° - 60°C for short periods) without 10 suffering temporary or permanent damage is expected to limit the use that can be made of SMA medical devices. It would thus be desirable to develop a way in which 15 the advantageous property of shape memory alloys, i.e. their ability to return to an original shape after relatively substantial deformation, could be used in medical devices without requiring the delicacy of alloying control and/or the temperature control of placement or removal needed by present shape memory alloy devices.

20 We have discovered that if, in a medical device containing a shape memory alloy element which uses the shape memory property of that alloy, an element which shows the property of stress-induced martensite is used instead, an improved device results.

25 Accordingly, a first aspect of the present invention provides a medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises an alloy element 30 which displays stress-induced martensite at said body temperature.

The device according to the present invention may, for example, be used as a heart valve, a catheter, for example a tracheal catheter, an intrauterine contraceptive device, a bone plate, a marrow nail, a dental arch 5 wire, a bone staple, or a clip.

A second aspect of the present invention provides a method of installing a pseudoelastic shape-memory alloy medical device within a mammalian body, or in such proximity to a mammalian body that the device is 10 substantially at body temperature wherein the pseudo-elastic shape-memory alloy medical device displays reversible stress-induced martensite at body temperature, the method comprising:

15 deforming the medical device into a deformed shape different from a final shape, said deforming occurring by the formation of stress-induced martensite;

restraining the deformed shape of the medical device by the application of a restraining means;

20 positioning the medical device and restraining means within, or in proximity to, the body;

removing the restraining means;

isothermally transforming the device from the deformed shape into the final shape.---

25 A third aspect of the present invention provides a method of installing a medical device within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, the method comprising:

manufacturing the medical device from a pseudo-
elastic shape-memory alloy wherein the pseudoelastic
shape-memory alloy medical device displays
reversible stress-induced martensite at body
temperature;

5

deforming the medical device into a deformed shape
different from a final shape, said deforming
occurring by the formation of stress-induced
martensite;

10

restraining the deformed shape of the medical
device by the application of a restraining means;

positioning the medical device and restraining
means within, or in proximity to the body;

removing the restraining means;

15

isothermally transforming the device from the
deformed shape into the final shape.--

20

A fourth aspect of the present invention provides a
medical device assembly for use within a mammalian
body or in such proximity to a mammalian body that the
medical device is substantially at body temperature,
comprising:

25

a medical device and a restraining means;

said medical device being made of a pseudoelastic
shape-memory alloy displaying reversible,
stress-induced martensite at body temperature;

said medical device being deformed by the formation of stress-induced martensite into a shape different from a final shape and then restrained in the deformed shape by said restraining means;

5 said medical device and said restraining means being positioned in the body whereupon the restraining means is removed and the medical device isothermally transforms from the deformed shape into the final shape.

10 The invention will now be described, by way of example, with reference to the accompanying drawings, wherein:

Figures 1 and 2 illustrate the stress-strain behavior of an alloy which exhibits constant stress versus strain behavior due to stress-induced martensite.

15 The invention will be discussed first by introducing the concept of stress-induced martensite and the effect achievable by its use, and then by examples showing how SIM alloy elements can be substituted for conventional SMA elements in medical devices to achieve the beneficial
20 effect of the invention.

The Figures illustrate the phenomenon of stress-induced martensite by means of stress-strain curves. In both Figure 1 and Figure 2, the alloy is at a temperature between M_s and M_d so that it is initially austenitic; and it will be assumed for the purposes of this discussion that M_s is equal to M_f , and A_s equal to A_f . Figure 1 shows the case when the temperature is below A_s , so that any martensite formed by the applied stress is stable; while Figure 2 shows the case where the temperature is above A_s , so that austenite is the only stable phase at zero stress.

In Figure 1, when a stress is applied to the alloy, it deforms elastically along the line OA. At a critical applied stress, σ_M , the austenitic alloy begins to transform to (stress-induced) martensite. This transformation takes place at essentially constant stress until the alloy becomes fully martensitic at point B. From that point on, as further stress is applied, the martensite yields first elastically and then plastically (only elastic deformation is shown at point C). When the stress is released, the martensite recovers elastically to point D, at which there is zero residual stress, but a non-zero residual strain. Because the alloy is below A_s , the deformation is not recoverable until heating above A_s results in a reversion to austenite. At that point, if the sample is unrestrained, the original shape will be essentially completely recovered: if not, it will be recovered to the extent permitted by the restraint. However, if the material is then allowed to re-cool to the original temperature at which it was deformed (or a temperature where SIM behavior of this type is seen), the stress produced in the sample will be constant regardless of the strain provided that the strain lies within the "plateau" region of the stress-strain curve. That is, for a strain between ϵ_B and ϵ_A , the stress will be σ_M . This means that a known, constant force (calculable from σ_M) can be applied over a wide (up to 5% or more for certain Ni/Ti alloys) strain range. Thus, though this resembles the conventional shape memory effect, because the alloy shows SIM and is below A_s a constant force can be achieved.

In Figure 2, when a stress is applied to the alloy, it deforms elastically along line OA, then by SIM along line AB, and by deformation of the martensite to point

C, just as in Figure 1. However, the stress-strain behavior on unloading is significantly different, since the alloy is above A_s and the stable phase is therefore austenite. As the stress is removed, the alloy recovers 5 elastically from C to D; then, at a critical stress, A , the alloy reverts to austenite without requiring a change in temperature. Thus reversion occurs at essentially constant stress. Finally if the stress is removed from the reverted austenite, it recovers 10 elastically along line E0. The recoverable deformation associated with the formation and reversion of stress-induced martensite has been referred to as pseudoelasticity. While M may be comparatively high, e.g. 345 MPa (50 ksi) A is usually substan- 15 tially lower, e.g. less than 69 MPa (10 ksi) thereby creating a constant-force spring with an effective working range of about 5% ($\varepsilon_B - \varepsilon_A$). The shape change available in the SMA is thus mechanically, rather than thermally, actuated and controlled, 20 permitting a greater control over a device incorporating it.

Suitable alloy for this invention i.e. those displaying stress-induced martensite at temperatures near mammalian body temperature (35° - 40° C), may be selected from known 25 SMAs by those of ordinary skill in the art, having regard to this disclosure by testing for the existence of the SIM effect at the desired temperature. A particularly preferred alloy is the nickel/titanium/vanadium alloy of copending U.S. Patent Application 30 No. 541844, referred to previously.

The invention will now be discussed in detail by some Examples of the use of an SIM alloy.

Example I. Heart Valves

Akins, in U.S. Patent No. 4,233,690, the disclosure of which is incorporated herein by reference, describes the use of a shape memory alloy ring to hold a sewing 5 cuff to the body of an artificial heart valve. The ring is made in the austenitic phase, cooled to the martensitic phase, deformed, placed around the valve body, and heated or allowed to warm to cause reversion to the austenitic phase and recovery of the ring into engagement 10 with the valve body.

However, this technique has not found commercial acceptance. Present medical technique requires that the valve body be capable of being rotated relative to the cuff, thereby enabling the surgeon to set the 15 rotational orientation of the valve after it has been sewn into place. This is desirable because the techniques used make it difficult to visualize or accomplish optimal orientation during initial placement.

In order to accomplish the desired torque control to 20 permit the desired rotation and yet ensure a firm hold of the cuff on the valve body, precise control of the pressure exerted on the valve body by the ring is needed. This is difficult because there are substantial 25 manufacturing tolerances in the valve body which may be made, for example, of pyrolytic graphite or ceramics, etc. Because the austenite stress-strain curve is extremely steep, it is not considered practical to use the simple shape memory technique proposed by Akins. Indeed, Akins does not even address the issue of 30 rotation of the cuff with respect to the valve body.

However, if an SIM alloy is used instead of conventional shape memory, the process may be considerably simplified.

First, if the alloy has a stress-strain curve like that of Figure 1, the alloy ring may be made just as for Akins. The ring is then expanded from its initial austenitic state by the formation of SIM. When the 5 ring is placed about the valve body, it needs only to be heated above A_f and allowed to cool to its original temperature for the ring to engage the valve body with a constant force, even if the valve body has a deviation from the specified size. The torque may thus be 10 controlled to the desired level despite manufacturing tolerances.

Second, if the alloy has a stress-strain curve like that of Figure 2, the ring may be expanded, placed over the valve body, and the stress released all at the same 15 temperature. Because the austenitic phase is stable, the stress-induced martensite spontaneously reverts to austenite until recovery is restrained by the ring engaging the valve body. Because the reversion to austenite takes place at constant stress, a constant 20 force (and hence constant torque) may be obtained regardless of manufacturing tolerances. Close temperature control is not required, either; and the fact that the patient in a heart valve replacement operation is conventionally cooled as much as 15°C or so below 25 normal body temperature does not affect the operation of the ring.

To control the torque at a sufficiently low level, it may be desirable for the alloy ring to be other than a solid ring, such as, for example, a continuous 30 helical spring, a flat zigzag spring, etc. Such variations permit the achievement of a greater range of movement with constant force and a reduction in the force exerted by the ring on the valve body, since the ring recovers in a bending mode rather than in tension.

Example II. Catheters And Cannulas

Wilson, in U.S. Patent No. 3,890,977, the disclosure of which is incorporated herein by reference, discloses a catheter or cannula (both being included hereinafter in the word "catheter") made of, or containing, an SMA element to cause all or a portion of the catheter to deploy in a useful form once introduced into a living body.

However, again this device has not been commercialized. Possible defects of the device which have prevented commercialization include (i) the inability slowly to emplace the catheter in a desired position when the transition temperature of the alloy is below body temperature (since the SMA element will attempt to revert to its original shape as it reaches body temperature), thus limiting the ability of the physician to place the device carefully and precisely; or alternatively, if the transition temperature of the alloy is above body temperature, the requirement that the device be heated to a temperature above body temperature to cause recovery and that the device be placed so as not to change shape again when it re-cools (since the body temperature is below the transition temperature); (ii) the inability to remove the device easily; and (iii) the need for controlled temperature storage to prevent premature reversion to austenite of the SMA, with consequent shape change.

The issue of removal of a catheter is especially significant, and not addressed by Wilson. Consider, for example, a tracheal puncture catheter. This should be straight for easy insertion into the trachea through

a puncture into the front of the neck, but should curve after insertion so that the flow of air or oxygen through the catheter passes axially down the trachea rather than impinging on the surface of the trachea and 5 damaging it. If a shape memory catheter is used as contemplated by Wilson, it would presumably become austenitic and bend after insertion (see Figures 1a and 1b, and corresponding text, of Wilson). But removal would require either cooling to below the transition 10 temperature (which could easily mean cooling to so low a temperature that the tracheal tissue is damaged), removal in the bent shape (presumably damaging tissue), or forcing the austenitic SMA to straighten to permit direct removal (unlikely to be satisfactory since the 15 austenitic alloys e.g. of Ni/Ti may have yield strengths of 690 MPa (100 ksi) or more, and force sufficient to cause plastic deformation would be required).

If an SIM element is used instead, however, removal can be accomplished almost as easily as insertion. If the 20 catheter is made in a bent shape (as in Wilson), it can be straightened by insertion of a straight pin down the catheter axis, the catheter deforming by the formation of stress-induced martensite. Insertion of the catheter into the trachea is accomplished while the catheter is 25 straight, at whatever rate is desired (permitting easy and accurate placement), and the pin is gradually withdrawn to permit the catheter to take up its desired shape as the martensite reverts to austenite. [It is assumed here that the stress-strain curve of the alloy 30 at the temperature of use is of the form of Figure 2, so spontaneous reversion occurs on removal of the stress induced by the pin]. When removal is desired, it may be achieved simply by the gradual insertion of the pin, straightening the catheter and permitting easy 35 withdrawal. Insertion of the catheter into the body

and pin removal may, of course, take place simultaneously if desired, as may pin reinsertion and removal of the catheter from the body.

Example III. IUDS

5 Fannon et al., in U.S. Patent No. 3,620,212, the disclosure of which is incorporated herein by reference, discloses an intrauterine contraceptive device (an IUD) proposed to be formed of a shape memory alloy. The device is suggested to be deformed in the martensitic 10 phase (the transition temperature being below the temperature of the uterus), and the deformed device insulated with, e.g., wax and inserted it. Removal is contemplated only by using two SMA elements in opposition, the higher temperature one being martensitic at body 15 temperature but strong enough so that, if heated, it will overcome the lower temperature element and deform the IUD back to a removable shape. The heating contemplated is electrical. The storage problem discussed in Example II also exists here, so that the 20 device must be stored below its transition temperature.

By the use of an SIM element, however, these disadvantages may be overcome. Again, assume that the alloy is SIM psuedoelastic, i.e. that it has the stress-strain curve of Figure 2. Then an IUD may be 25 formed into the desired shape in the austenitic state, and deformed by compression into a tubular placement device (the deformation being such that the strain levels lie within the "plateau" of the stress-strain curve). When the placement device is inserted into 30 the uterus, the IUD may be deployed by extrusion of the IUD from the placement device. Deployment is then controlled but immediate, so that the physician may satisfy himself with placement. Removal is the reversal

of placement: the placement device is inserted into the uterus, the IUD deformed by withdrawal into the placement device, and the placement device withdrawn. Temperature control is not required.

5 Example IV. Bone Plates

Johnson et al., in U.S. Patent No. 3,786,806, the disclosure of which is incorporated herein by reference, propose the use of Ni/Ti SMA bone plates in fracture fixation. The plate is deformed in its martensitic state, screwed to the two ends of the bone it is desired to compress together, and warmed (or allowed to warm) to the austenitic state, when the plate contracts, compressing the bone ends together.

Because of the high elastic moduli of the austenitic shape memory alloys, it will be difficult to control the amount of force which may be applied by a bone plate of the type proposed by Johnson et al., and precision placement of the bone ends and elongation of the plate will be required.

20 If, however, an SIM pseudoelastic bone plate is used, it will be easily possible to elongate the plate and fasten it to the bone ends without requiring high precision. Because of the comparatively large (e.g. 5%) strain range at essentially constant stress, the 25 force which will be put on the bone ends to compress them will be readily adjustable (by the size of the plate, for example) and will be insensitive to precise placement of the bone ends and/or elongation of the plate. Also, the recovery of the plate, since it is controlled by mechanical restraint, may be as 30 gradual as desired, achieving excellent force and time control, and permitting the surgeon to make adjustments as desired.

Example V. Marrow Nails

Baumgart et al., in U.S. Patent No. 4,170,990, the disclosure of which is incorporated herein by reference, discloses the use of the two-way shape memory effect (where an SMA element exhibits a first shape in the austenitic state and a second in the martensitic state, and spontaneously changes between the two shapes with a change in temperature) in, inter alia, marrow nails (see Figures 1a through 1e, and corresponding text, of Baumgart et al.).

The method proposed, however, requires the use of a wide temperature range in order to cause the phase change which is the origin of the two-way shape memory effect (5°C to 60°C for the water used to cool or heat the nail). In addition, it requires the manufacture of two-way shape memory elements, which is generally more complex than the manufacture of conventional shape memory elements; and precise control of the transition temperature is required.

However, if an SIM pseudoelastic alloy element is employed, these disadvantages may be overcome. If internal tangs, which may be gripped by an inserted tool, are provided within a marrow nail of the type shown in Figure 1a of Baumgart et al., then the nail may be radially compressed by the application of stress by such a tool. When the nail is released by the tool, it will expand to fill the bone channel with a constant force (not readily available by Baumgart et al.); and it may be withdrawn by the reverse procedure.

Example VI. Dental Arch Wire

Andreasen, in U.S. Patent No. 4,037,324, the disclosure of which is incorporated herein by reference, proposes the use of dental arch wires made of Ni/Ti alloys

5 instead of conventional 18-8 stainless steel wires. The wires are stated to be of lower elastic modulus and higher elastic limit than stainless steel, which is stated to be advantageous. Heat recovery of an SMA wire is also suggested as a technique for orthodonture.

10 The technique of using the conventional shape memory effect is not believed to have found clinical application, possibly because such a technique would require rapid placement of the wire in its martensitic state to avoid premature recovery, and would result in rapid recovery 15 with extremely high forces, which would be painful for the patient.

The use of a wire which displays lower elastic modulus and higher elastic limit than stainless steel has found some application, however. Otsuka et al. in Metals

20 Forum, v. 4, pp. 142-52 (1981) have suggested that this behavior may be the result of elasticity enhanced by cold working and martensite-to-martensite pseudoelasticity in an alloy which has a transition temperature below body temperature. The alloy, then, is martensitic 25 rather than austenitic in its undeformed state.

While the use of an enhanced elasticity wire may offer some advantages over the more usual stainless steel wire, it remains the situation that the amount of motion in the teeth that may be produced by an arch 30 wire without further adjustment is largely limited by the pain tolerance of the patient (since the force

is largely limited by the pain tolerance of the patient applied by the arch wire is proportional to the deformation of the wire). However, if an SIM pseudoelastic wire is used, it can exert a relatively constant force 5 (chosen by the dentist to be sufficient to cause tooth movement but not painful) over a strain range of up to 5%. The load may be applied mechanically, and is thus more readily established, and no precise temperature control of the alloy is needed as would be required for 10 the shape memory effect.

Example VII. Coil Stents and Filters

The use of tubular coiled wire stent grafts has been discussed in the medical literature since 1969. Although the coils helped maintain patency of the 15 vessels in which they were placed, they were difficult of insertion unless narrow enough to significantly narrow the lumen of the vessel. Recently it has been proposed, see Radiology, v. 147, pp. 259-60 and pp. 261-3 (1983), the disclosures of which are incorporated 20 herein by reference, to use SMA wire to form these tubular coils. The wire, which has a transformation temperature below body temperature, is introduced through a catheter after being straightened in its martensitic state. When the wire is heated, the coil 25 re-forms.

Because of the difficulty of controlling the transformation temperature accurately, it has proved necessary to cool the straightened wire during insertion and/or to heat the wire to form the coil after insertion. These 30 procedures add to the complexity of the operation.

If an SIM pseudoelastic wire is used to form the coil, which is then isothermally deformed by loading into a catheter, then the need for temperature control is avoided. The wire remains straight when in the

5 catheter, but re-forms the coil spontaneously when it is extruded from the catheter. Accurate placement is thus readily obtainable, since there is no urgency as might be required with a conventional shape memory effect element.

10 It has similarly been proposed to use SMA wire to form a filter for emplacement by catheter in the vena cava to trap blood clots. The filter is formed in the austenitic state, the wire straightened in the martensitic state and inserted, and the filter re-forms

15 on warming. Just as for the coil stents discussed above, the use of an SIM pseudoelastic wire would greatly simplify manufacture and insertion of such a vena cava filter, permitting accurate placement with no need for urgency or temperature manipulation.

20 Example VIII. Bone Staples, Clips, etc.

Bone staples are frequently used to hold fragments of fractured bone together when the fracture is fixed, and may be used in some cases as a replacement for bone plates in the same situation. Sometimes the staples

25 are inserted into drilled holes, sometimes merely driven into the bone directly.

It would be desirable to have a bone staple which provided a controlled force between the tines which would tend to hold the staple in place. Shape memory

30 alloys have been proposed for this application, but again the problem of accurate placement while operating quickly enough to prevent the shape change associated with the martensite-to-austenite transition and/or the

need for temperature control complicate their use.

If an SIM alloy is used, these disadvantages may be readily overcome. If the alloy is below A_s , it may be emplaced in the martensitic state. Brief heating 5 will then be required to cause it to become austenitic, but on recooling to body temperature, a constant force can be achieved. If the alloy is above A_s , the staple can be held deformed by a moderate force, then released after insertion to also provide an accurately- 10 known force. In either event, removal is easier than if the alloy is purely austenitic, as discussed above for Examples II and V, for example.

Similarly, SIM alloy (especially alloy which is pseudoelastic, above A_s at its utilization temperature) 15 may be used to manufacture vascular clips, etc. The alloy element here acts as a constant force spring over a wide strain range (greater than conventional elastic metals), resulting in ease of use.

From the foregoing, it is clear that, in a situation 20 where narrow temperature differences are available or preferable, as often is the case in medical applications, mechanically constrained shape change is a much more useful solution than heat actuated shape change. It offers a degree of control heat actuation does not, it 25 offers easier alloy composition control, it eases mating part tolerance requirements, and it offers simple mechanical reversal at minimal stress levels, all without heating, cooling or insulation complications.

CLAIMS:

1. A medical device intended for use within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, which device comprises an alloy element which displays 5 stress-induced martensite at said body temperature.
2. A device according to claim 1 which is a heart valve, the alloy element being a ring employed to hold a sewing cuff onto the valve body.
3. A device according to claim 1 which is a catheter, 10 the alloy element being the catheter or a part thereof which causes the catheter to assume a bent shape.
4. A device according to claim 3 which is a tracheal catheter.
5. A device according to claim 1 which is an 15 intrauterine contraceptive device or a bone plate, or a marrow nail.
6. A device according to claim 1 which is a dental arch wire, or a bone staple or a clip.
7. A method of installing a pseudoelastic shape-memory 20 alloy medical device within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature wherein the pseudo-elastic shape-memory alloy medical device displays reversible stress-induced martensite at body temperature, 25 the method comprising:

deforming the medical device into a deformed shape different from a final shape, said deforming occurring by the formation of stress-induced martensite;

5 restraining the deformed shape of the medical device by the application of a restraining means;

positioning the medical device and restraining means within, or in proximity to, the body;

removing the restraining means;

10 isothermally transforming the device from the deformed shape into the final shape.--

8. A method of installing a medical device within a mammalian body, or in such proximity to a mammalian body that the device is substantially at body temperature, 15 the method comprising:

manufacturing the medical device from a pseudoelastic shape-memory alloy wherein the pseudoelastic shape-memory alloy medical device displays reversible stress-induced martensite at 20 body temperature;

deforming the medical device into a deformed shape different from a final shape, said deforming occurring by the formation of stress-induced martensite;

25 restraining the deformed shape of the medical device by the application of a restraining means;

positioning the medical device and restraining means within, or in proximity to the body;

removing the restraining means;

5 isothermally transforming the device from the deformed shape into the final shape.--

9. A medical device assembly for use within a mammalian body or in such proximity to a mammalian body that the medical device is substantially at body temperature, comprising:

10 a medical device and a restraining means;

said medical device being made of a pseudoelastic shape-memory alloy displaying reversible, stress-induced martensite at body temperature;

15 said medical device being deformed by the formation of stress-induced martensite into a shape different from a final shape and then restrained in the deformed shape by said restraining means;

20 said medical device and said restraining means being positioned in the body whereupon the restraining means is removed and the medical device isothermally transforms from the deformed shape into the final shape.

0145166

1/1

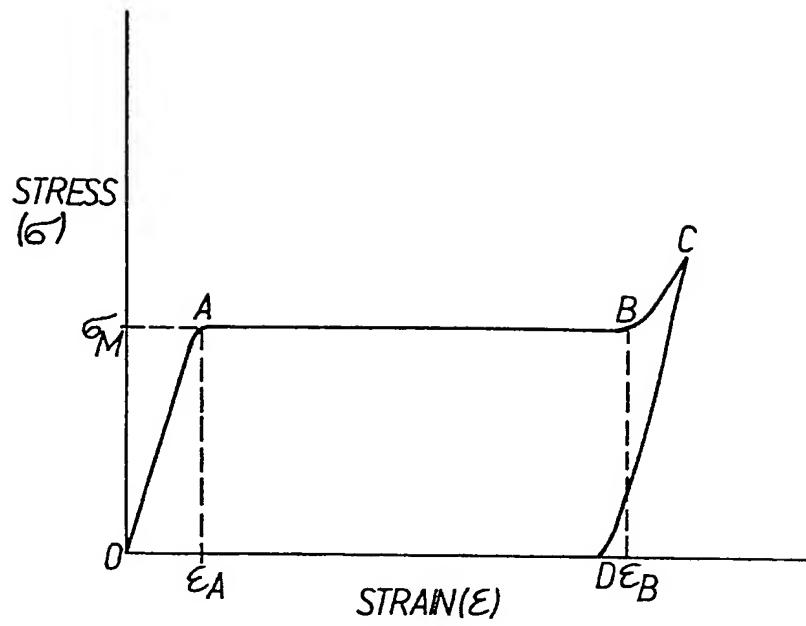


Fig.1.

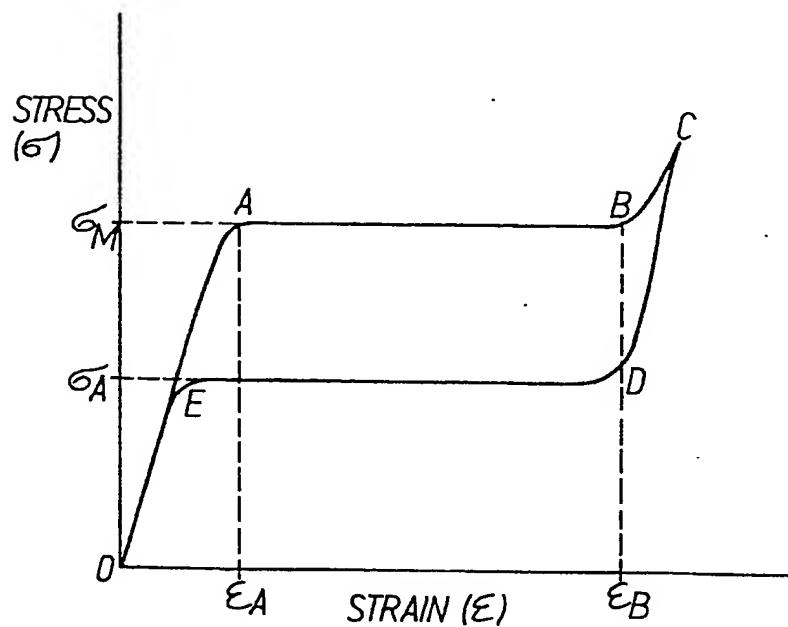


Fig.2.

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- BLACK BORDERS**
- IMAGE CUT OFF AT TOP, BOTTOM OR SIDES**
- FADED TEXT OR DRAWING**
- BLURRED OR ILLEGIBLE TEXT OR DRAWING**
- SKEWED/SLANTED IMAGES**
- COLOR OR BLACK AND WHITE PHOTOGRAPHS**
- GRAY SCALE DOCUMENTS**
- LINES OR MARKS ON ORIGINAL DOCUMENT**
- REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY**
- OTHER:** _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.